UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,147	07/06/2001	Robert Burgermeister	CRD-949	2811

27777 7590 06/03/2004

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
BAXTER, JESSICA R	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,147	BURGERMEISTER ET AL.	
	Examiner	Art Unit	
	Jessica R Baxter	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 3, 5, 6 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,190,406 to Duerig et al.

Regarding claims 1 and 25, Duerig discloses a stent in the form of a thin-walled, multi-cellular, tubular structure having a longitudinal axis, the stent comprising a multiplicity of circumferential sets of strut members (FIG. 4), each set of strut members being longitudinally separated each from the other, each set of strut members being connected to adjacent sets of strut members by longitudinal connecting links (70) and each set of strut members forming a closed, ring-like cylindrical portion of the stent (52(a)-52(d)), each set of strut members consisting of a multiplicity of connected curved sections (62) connected by straight diagonal sections (portions connecting loops 62), each curved section having two ends and a center situated there between, at least one set of strut members having at least half of the curved sections within the set of strut members having a tapered shape wherein the width at the center of a curved section with a tapered shape is greater than the width at the ends of a curved section with tapered shape such that the curved section tapers outwardly from its center toward both of said curved section ends so that the width of said

curved section is continually narrowing toward the ends of the curved section (see loops 62 in FIG. 4).

Regarding claim 2, Duerig discloses that the curved sections of one or more of the sets of strut members have inside and outside surfaces in the shape of circular arcs each circular arc having a center of curvature with the centers of curvature of the two arcs being longitudinally displaced one from the other (Column 5 lines 41-43).

Regarding claim 5, Duerig discloses that one or more of the curved sections of the sets of strut members have a tapered shape with a greater width at the center of the curved section compared to the width at the center of at least one diagonal section (see center of struts FIG. 4).

Regarding claim 6, Duerig discloses that all curved sections have a tapered shape (FIG. 4).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. '406 in view of U.S. Patent No. 5,913,895 to Burpee et al.

Duerig discloses the claimed invention except for the each individual flexible link consisting of a multiplicity of individual flexible links, each link being a single undulating structure that extends generally in the longitudinal direction. Burpee teaches that undulating

links provide increased flexibility (Column 2 lines 39-60). It would have been obvious to one having ordinary skill in the art to replace the links of Duerig with the undulating links of Burpee in order to enhance the flexibility of the device.

5. Claims 7-11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. '406 in view of U.S. Patent No. 6,273,910 to Limon.

Duerig discloses the claimed invention except for thee end sets of strut members having shorter diagonal sections as compared to the length of the diagonal sections of the central sets of strut members. Limon teaches that the end sets of strut members may be made shorter in order to increase resistance to circumferential deformation, increase resistance to radial expansion and thus control the radial expansion of the stent (Column 3 lines 29-48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent of Duerig with the shortened diagonal sections in the end portions in order to increase the stents resistance to circumferential deformation, increase the resistance to radial expancion and thus control the radial expansion of the stent.

6. Claims 15, 16, 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. '406 in view of U.S. Patent No. 5,609,629 to Fearnot et al.

Duerig discloses the claimed invention except for the coating of the stent with a plastic material containing parylene and a drug of heparin. Fearnot teaches that parylene is well known for use in the biomedical field (see Column 4 lines 5-12). Fearnot also teaches that bioactive layers can be attached to the porous layer of parylene in order to ensure a controlled release of the bioactive substance (see Column 4 lines 23-39). Fearnot also teaches that heparin may be provided on the stent since it is an antiplatelet or antithrombotic agent (see Column 3 lines 30-49). It would have been obvious to one having ordinary skill in

the art at the time the invention was made to provide a coating of parylene and heparin on the stent of Duerig in order to provide a controlled release of a drug and to provide a drug with antiplatelet or antithrombotic properties.

7. Claims 15, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. '406 further in view of U.S. Patent No. 6,273,913 to Wright et al.

Duerig discloses the claimed invention except for the coating of the stent with a polymer containing rapamycin. Wright teaches that rapamycin is capable of inhibiting an inflammatory response caused by stent implantation (see Column 5 lines 36-46). Wright also teaches that a polymer is provided to hold the drug to the stent (see Column 6 lines 1-2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent of Duerig with a polymer coating in order to hold a drug on the body of the stent and to provide the stent of Duerig with the drug of rapamycin in order to inhibit the inflammatory response that s caused by the implantation of the stent itself.

8. Claims 15, 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. '406 in view of Fearnot et al.'629, further in view of U.S. Patent No. 6,231,600 to Zhong.

Duerig, as modified, discloses the claimed invention except for the coating of the stent with a plastic material that contains the drug Taxol or heparin. Zhong teaches that Taxol or heparin is provided in a polymeric coating in order to release the drugs over a period of time. Zhong teaches that taxol and heparin render the stent non-thrombogenic to prevent the occurrence of restenosis (see Column 2 lines 24-42). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent

of Duerig, as modified, with the polymeric coating that contains heparin or taxol in order to make the stent of Duerig non-thrombogenic in order to prevent restenosis.

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. '406 in view of Fearnot et al. '629 as applied to claims 15, 16, and 17, further in view of U.S. Patent No. 6,368,658 to Schwarz et al.

Duerig, as modified, discloses the claimed invention except for the use of phosphorylcholine. Schwarz teaches that phosphorylcholine is a well-known material that can be applied to stents for drug delivery (see Column 6 lines 32-57 and Column 15 lines 41-53). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent of Duerig with phosphorylcholine since it is well known in the art to use phosphorylcholine in drug delivery stents.

10. Claims 15 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. '406 in vie w of U.S. Patent No. 5,725,572 to Lam et al.

Duerig discloses the claimed invention except for the polymer coating that contains a radiopaque material. Lam teaches that providing the stent with a radiopaque marker in the coating allows the stent to be located using fluoroscopy without obscuring the lesion that is to be repaired and without impeding the deformation of the expandable stent (see Abstract and Column 7 lines 14-27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent of Duerig with a polymeric coating containing a radiopaque material in order to locate the position of the stent without obscuring the lesion or impeding the deformation of the expandable stent.

11. Claims 15, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. '406 in vie w of U.S. Patent No. 6,066,169 to McGuinness.

Duerig discloses the claimed invention except for the polymer coating containing tungsten. McGuinness teaches that polymers and tungsten are well known materials to be used in stents (see Column 6 lines 46-52). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent of Duerig with a coating containing tungsten and a polymer since these are well known materials employed in stents.

12. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. '406 in view of Lam et al. '572 as applied to claim15 and 22 above, and further in view of U.S. Patent No. 5,634,946 to Slepian.

Duerig, as modified discloses the claimed invention except for the thickness of the coating on the stent. Slepian discloses that the coating of a stent can be customized for an individual clinical situation (see Column 6 lines 45-50). Slepian discloses that varying thicknesses of the coating can be achieved to achieve a required geometry to completely occlude a vessel or deliver therapeutic agents to a specific location (see Column 8 line 66-Column 9 line 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coating of the modified stent of Duerig in order to achieve a geometry for a specific clinical application of the stent including the occlusion of a lumen or the delivery of a therapeutic agent.

Response to Arguments

13. Applicant's arguments filed April 15, 2004 have been fully considered but they are not persuasive.

Applicant argues that Duerig et al. '406 does not disclose continuously tapered curved sections. From Figure 4, a portion of which is attached below, it appears that the curved sections are tapered. Therefore, the rejection over Duerig et al. '406 is proper.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on 703-308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter
Examiner
Art Unit 3731

jrb

DAVID O. REIP
PRIMARY EXAMINER